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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,447	03/29/2004	Matthew Baker	293/059	4689

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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/813,447	BAKER ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-15,17-20 and 35-40* is/are rejected.

7)☒ Claim(s) *9, 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation " the plurality of inside-retention members" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitations "the loading tool" and "the cannulation" in line 2. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6-8, 10, 17, 18 and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Logan et al. (PCT US00/15259).

Regarding Claim 1, Logan teaches a connector assembly (200) for use in making an anastomotic connection between an opening prepared at an end of a graft tissue (122) conduit and an aperture in a side wall of a body tissue conduit in a patient comprising: a body disposed annularly about a longitudinal axis and having axially spaced distal and proximal portions, the distal portion having a graft retention component (202) to secure the tissue of the graft tissue conduit about the opening to the connector assembly (200), and the proximal portion having a plurality of annularly

spaced body fingers (204) that expand radially out to engage the interior surface of the side wall of the body tissue conduit about the aperture (Column 7, proximate lines 25-27).

Regarding Claims 2 and 39, Logan teaches the connector assembly defined in claims 1 and 35, wherein the graft retention component (202) comprises an annular inside-retention element configured to engage the interior surface of the graft tissue conduit about the opening (fig. 4).

Regarding Claims 3 and 40, Logan teaches the connector assembly defined in claims 2 and 37, wherein the annular inside-retention element has a cross-sectional area larger than the cross-sectional area of the graft tissue conduit (fig. 4).

Regarding Claim 4, Logan teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (202) is unitary with the distal portion of the body (208).

Regarding Claim 6, Logan teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (202) includes a plurality of annularly spaced inside-retention members that have free ends configured to engage the interior surface of the graft tissue conduit about the opening (fig. 4).

Regarding Claim 7, Logan teaches the connector assembly defined in claim 2, wherein the connector assembly further comprises an outside-retention element configured to annularly engage the exterior surface of the graft tissue conduit about the opening (outwardly extending barb portions of retention element 202, fig. 13).

Regarding Claim 8, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element comprises a plurality of annularly spaced outside-retention members (fig. 13).

Regarding Claim 10, Logan teaches the connector assembly defined in claim 7, wherein the outside-retention element is rigidly connected to the distal portion of the body (fig. 12).

Regarding Claim 17, Logan teaches the connector assembly defined in claim 1, wherein the radially outward expansion of the plurality of annularly spaced body fingers (204) is an elastic bending (fig. 31).

Regarding Claim 18, Logan teaches the connector assembly defined in claim 1, wherein the body has a medial portion between the proximal portion and the distal portion, wherein the medial portion includes at least one torsional element (206).

Regarding Claim 35, Logan teaches an apparatus for producing the anastomotic connection between the opening prepared at the end of the graft tissue conduit and the aperture in the side wall of the body tissue conduit in the patient comprising: the connector assembly defined in claim 1; and a delivery tool (100) having a first configuration and a second configuration, wherein the first configuration is configured for deforming the proximal portion of the connector assembly from an expanded configuration to a deformed configuration and to advance the deformed proximal portion of the connector assembly into the lumen of the body tissue conduit via the aperture (fig. 15a), and wherein the second configuration is configured for un-deforming the

proximal portion of the connector assembly in the lumen of the body tissue conduit (fig. 30).

Regarding Claim 36, Logan teaches the apparatus defined in claim 35, wherein the loading tool is external to the cannulation of the connector assembly (fig. 5).

Regarding Claim 37, Logan teaches the apparatus defined in claim 35 further comprising a loading tool (134) having a body portion, wherein the body portion is configured to support the distal portion of the connector assembly and to define the resulting shape of the anastomotic connection external to the body tissue conduit (fig. 6).

Regarding Claim 38, Logan teaches the apparatus defined in claim 37, wherein the loading tool further comprises at least one tissue holder (190) configured to engage the exterior surface of the graft tissue conduit about the opening and to hold the graft tissue conduit about the graft retention component of the connector assembly (fig. 12).

Claims 1-7, 11-15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Sancoff et al. (US 6682540).

Regarding Claim 1, Sancoff teaches a connector assembly (10) for use in making an anastomotic connection between an opening prepared at an end of a graft tissue (55) conduit and an aperture in a side wall of a body tissue conduit (65) in a patient comprising: a body disposed annularly about a longitudinal axis and having axially spaced distal and proximal portions, the distal portion having a graft retention component (30) to secure the tissue of the graft tissue conduit about the opening to the

connector assembly (10), and the proximal portion having a plurality of annularly spaced body fingers (45) that expand radially out to engage the interior surface of the side wall of the body tissue conduit about the aperture (fig. 5c).

Regarding Claim 2, Sancoff teaches the connector assembly defined in claim 1, wherein the graft retention component (30) comprises an annular inside-retention element (25) configured to engage the interior surface of the graft tissue conduit about the opening (fig. 5c).

Regarding Claim 3, Sancoff teaches the connector assembly defined in claim 2, wherein the annular inside-retention element has a cross-sectional area larger than the cross-sectional area of the graft tissue conduit (fig. 5c).

Regarding Claim 4, Sancoff teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (25) is unitary with the distal portion of the body (30, it is noted that the term unitary is vague and may be interpreted as two portions as one).

Regarding Claim 5, Sancoff teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (25) is coupled to the distal portion of the body.

Regarding Claim 6, Sancoff teaches the connector assembly defined in claim 2, wherein the annular inside-retention element (25) includes a plurality of annularly spaced inside-retention members that have free ends configured to engage the interior surface of the graft tissue conduit about the opening (fig. 5c).

Regarding Claim 7, Sancoff teaches the connector assembly defined in claim 2, wherein the connector assembly further comprises an outside-retention element (85) configured to annularly engage the exterior surface of the graft tissue conduit about the opening (fig. 5c)

Regarding Claim 11, Sancoff teaches the connector assembly defined in claim 7, wherein the outside-retention element (85) is slidably coupled to the distal portion of the body (fig. 5a-5c).

Regarding Claim 12, Sancoff teaches the connector assembly defined in claim 7, wherein the outside-retention element (85) is further configured to engage the exterior surface of the body tissue conduit about the opening

Regarding Claim 13, Sancoff teaches the connector assembly defined in claim 7, wherein the outside-retention element is configured to be at least partially proximal to the plurality of inside-retention members (25, fig. 5c).

Regarding Claim 14, Sancoff teaches the connector assembly defined in claim 7, wherein the outside-retention element (85) is configured to be at least partially in the same plane as the inside-retention element (25).

Regarding Claim 15, Sancoff teaches the connector assembly defined in claim 7, wherein the outside-retention element (85) is a substantially annular expandable band configured to pass annularly about the plurality of inside-retention members from a first position distal to the plurality of inside-retention members (fig. 5a) to a second position at least partially proximal to the plurality of inside-retention members (fig. 5c).

Regarding Claim 17, Sancoff teaches the connector assembly defined in claim 1, wherein the radially outward expansion of the plurality of annularly spaced body fingers (45) is an elastic bending (Columns 3-4, proximate lines 64-67 and 1-5 respectively).

Regarding Claim 18, Sancoff teaches the connector assembly defined in claim 1, wherein the body has a medial portion between the proximal portion and the distal portion, wherein the medial portion includes at least one torsional element (20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff in view of Scholz et al. (US 6273912).

Sancoff teaches all limitations of preceding dependent claim 1, but fails to teach wherein the opening is prepared by a length-wise axial incision from a toe point at the

end of the graft tissue conduit to a heel point along the length of the graft tissue conduit, or wherein the opening is prepared by an incision oblique to the longitudinal axis of the graft tissue conduit from a toe point at the end of the graft tissue conduit to a first point along the length of the graft tissue conduit followed by a length-wise axial incision from the first point to a heel point further along the length of the graft tissue conduit. Scholz teaches a graft for end to side anstomosis wherein the opening is formed either by a length-wise axial incision from a toe point at the end of the graft tissue conduit to a heel point along the length of the graft tissue conduit (fig. 4b), or an incision oblique to the longitudinal axis of the graft tissue conduit (fig. 6b) in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Sancoff by preparing the opening as taught by Scholz in order to facilitate the anastomosis, increase compliance matching between the graft and the receiving artery, and optimize hemodynamic flow from the graft into the receiving artery.

Allowable Subject Matter

Claims 9 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
2/7/07

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
2/19/07.